COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL

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- 2. Defendant Merck & Co., Inc., (hereafter, "Merck") is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business in New Jersey. Merck was and is authorized to do business in the State of California and was engaged in substantial commerce and business activity in the County of San Francisco.
- 3. Defendant McKesson Corporation (hereafter, "McKesson") was and is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business in San Francisco, California. McKesson was and is authorized to do business in the State of California and was engaged in substantial commerce and business activity in the County of San Francisco.
- 4. The true names or capacities, whether individual, corporate, or otherwise, of Defendants Does 1-50, are unknown to Plaintiffs who therefore sue said Defendants by such fictitious names. Plaintiffs believe and allege that each of the Defendants designated herein by fictitious names is in some manner legally responsible for the events and happenings herein referred to and proximately caused foreseeable damages to Plaintiffs as alleged herein.
- 5. At all times herein mentioned, "Defendants" include all named Defendants herein as well as Defendants Does 1-50.
- 6. At all relevant times Defendants, through their agents, servants, employees and apparent agents, were the designers, manufacturers, marketers, distributors and/or sellers of Fosamax, a bisphosphonate drug used primarily to mitigate or reverse the effects of osteoporosis, osteopenia, and Paget's Disease.
- 7. Defendants, either directly or through their agents, apparent agents, servants or employees, at all relevant times, sold and distributed Fosamax in the State of California.

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- 8. Defendants derive substantial revenue from pharmaceutical products used or consumed in the State of California.
- 9. Defendants expected or should have expected, that their business activities could or would have consequences within the State of California.
- 10. Plaintiffs bring this action to recover damages, restitution, refunds. loss of consortium and/or for equitable, injunctive and declaratory relief against Defendants.
- 11. Defendants placed Fosamax into the stream of worldwide commerce and interstate commerce in the United States. It did so without adequate testing and with no warning that the drug carried with it a risk of causing osteonecrosis of the jaw.

SUMMARY OF THE CASE

- 12. Defendants, either directly or through their agents, apparent agents, servants or employees, designed, manufactured, marketed, advertised, distributed and sold Fosamax for the treatment of osteoporosis, Paget's disease, and other uses.
- 13. Defendants, either directly or through their agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed and sold Fosamax for the treatment of osteoporosis, Paget's disease, and other uses.
- 14. As a result of the defective nature of Fosamax, persons who were prescribed and ingested Fosamax, including Plaintiff Jennifer Bogard, have suffered and may continue to suffer severe and permanent personal injuries, including osteonecrosis of the jaw.
- 15. Defendants concealed and continue to conceal its knowledge of Fosamax's unreasonably dangerous risks from Plaintiff Jennifer Bogard, other consumers, and the medical community.
 - 16. Defendants failed to conduct adequate and sufficient post marketing

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surveillance of Fosamax after it began marketing, advertising, distributing, and selling the drug.

17. As a result of Defendants' actions and inaction, Plaintiff Jennifer Bogard was injured due to ingestion of Fosamax, which has caused and will continue to cause Plaintiff Jennifer Bogard various injuries and damages. Plaintiff Jennifer Bogard accordingly seeks compensatory damages.

FACTUAL BACKGROUND

- At all relevant times Defendant was responsible for, or involved in, 18. designing, manufacturing, marketing, advertising, distributing, and setting Fosamax.
- In September 1995, the United States Food and Drug Administration 19. ("FDA") approved Merck's compound alendronate for various uses, including the treatment of osteoporosis and Paget's Disease. Alendronate is marketed by Defendants as Fosamax.
- 20. Fosamax falls within a class of drugs known as bisphosphonates. Bisphosphonates are used for treating bone conditions such as osteoporosis and Paget's Other drugs within this class, such as Aredia and Zometa, are used as Disease. chemotherapy and as adjunct chemotherapy, but are not indicated for use in non-cancerous conditions such as osteoporosis.
- 21. There are two classes of bisphosphonates: the N-containing (nitrogenous) and the non-N-containing (non nitrogenous) bisphosphonates. The nitrogenous bisphophonates include the following: pamidronate (Aredia), ibandronate (Bondronat), and alendronate (Fosamax). The non-nitrogenous bisphosphonates include the following: etridonate (Didronel), clodronate (Bonefos and Loron), and tiludronate (Skelid). Alendronate contains a nitrogen atom. The Physicians Desk Reference ("PDR") for Fosamax confirms that the molecule contains a nitrogen atom.
 - Throughout the 1990's and 2000's, medical articles and studies

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appeared reporting the frequent and common occurrence of osteonecrosis of the jaw within chemotherapy patients taking nitrogenous bisphosphonates. As with its reported and acknowledged side effects concerning irritation, erosion, and inflammation of the upper gastrointestinal tract, Defendants knew or should have known that Fosamax, as a nitrogenous bisphosphonate, shared an adverse event profile similar to the other drugs within this specific subclass of bisphosphonates (i.e., those containing nitrogen).

- 23. Defendants knew and or should have known that bisphosphonates, including Fosamax, inhibit endothelial cell function. Similarly, Defendants knew or should have known that bisphosphonates also inhibit vascularization of the affected area and induce ischemic changes specific to patients' mandibles (lower jaws) and maxillae (upper jaws) and that these ischemic changes appear to be cumulative in nature.
- 24. Defendants also knew or should have known that these factors combine to create a compromised vascular supply in the affected area. As a result, a minor injury or disease can turn into a non-healing wound, which can progress to widespread osteomyelitis (inflammation of bone marrow) and ultimately osteonecrosis (bone death).
- Dentists are now being advised by dental associations to refrain from 25. undertaking any invasive procedure (such as drilling a cavity) for any patient on Fosamax.
- Once the osteonecrosis begins and becomes symptomatic, it is very 26. difficult to treat and typically is not reversible.
- 27. Shortly after Defendants began selling Fosamax, reports of onteonecrosis of the jaw and other dental complications among users began surfacing, indicating that Fosamax shared the class effects of the other nitrogenous bisphosphonates. Despite this knowledge, Defendants failed to implement further studies regarding the risk of osteonecrosis of the jaw relative to Fosamax. Rather than evaluating and verifying the safety of Fosamax with respect to osteonecrosis of the jaw, Defendants proposed further

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uses of Fosamax, such as Fosamax-D, and sought to extend the exclusivity period of Fosamax through 2018.

- Osteonecrosis of the jaw is a serious medical event and can result in 28. severe disability and death.
- Since Fosamax was released, the FDA has received a significant 29. number of reports of osteonecrosis of the jaw among users of Fosamax.
- On August 25, 2004 the United States Food & Drug Administration 30. ("FDA") posted its ODS Post marketing Safety Review on bisphosphonates, specifically pamidronate (Aredia), zoledronic acid (Zometa), risedronate (Actonel), and alendronate This was an epidemiologic review of the FDA adverse events database conducted by the FDA's Division of Drug Risk Evaluation.
- As a result of the FDA Review, the FDA observed that the risk of 31. osteonecrosis of the jaw was not confined to bisphosphonates used for chemotherapy. The FDA's review indicated that the osteonecrosis of the jaw was a class effect which specifically extended to the oral bisphosphonate, Fosamax.
- As a result, the FDA recommended and stated that the labeling for 32. Fosamax should be amended by Merck to specifically warn about the risk of osteonecrosis of the jaw. Defendants have refused to accede to the FDA's request and, to this day, still do not adequately warn of the risk of osteonecrosis of the jaw in its Fosamax labeling.
- 33. Rather than warn patients and despite knowledge known by Defendants about increased risk of osteonecrosis of the jaw on patients using Fosamax, Defendants continue to defend Fosamax, mislead physicians and the public, and minimize unfavorable findings.
- Fosamax is one of the Defendants' top selling drugs, averaging more 34. than \$3 billion a year in sales.

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	35.	Consumers, including Plaintiff Jennifer Bogard, who have used
Fosamax for	treatme	nt of osteoporosis, have several alternative safer products available to
treat the con-	ditions.	

- Defendants knew of the significant risk of dental and oral 36. complications caused by ingestion of Fosamax, but Defendants did not adequately and sufficiently warn consumers, including Plaintiff Jennifer Bogard, or the medical community, of such risk.
- As a direct result, Plaintiff Jennifer Bogard was prescribed Fosamax 37. and has been permanently and severely injured, having suffered serious consequences from the ingestion of Fosamax. Plaintiff Jennifer Bogard requires and will in the future require ongoing medical care and treatment.
- Plaintiff Jennifer Bogard has suffered mental anguish from the 38. knowledge that she will have life-long complications as a result of injuries sustained from the use of Fosamax.
- 39. Plaintiff Jennifer Bogard was prescribed and used Fosamax in a foreseeable manner pursuant to their respective prescriptions.
- 40. Plaintiff Jennifer Bogard, as a direct and proximate result of using Fosamax, suffered severe mental and physical pain and suffering and has sustained permanent injuries and emotional distress.
- 41. Plaintiff Jennifer Bogard used Fosamax which had been provided in a condition that was substantially the same as the condition in which it was manufactured and sold.
- 42. Plaintiff Jennifer Bogard would not have used Fosamax had Defendants properly disclosed the risks associated with the drug. Alternatively, Plaintiff Jennifer Bogard would have known and/or recognized the precursor events of osteonecrosis

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of the jaw and would have been able to avoid the clinical manifestation of the disease.

- Defendants, through their affirmative misrepresentations and 43. omissions, actively concealed from Plaintiff Jennifer Bogard and her physicians the true and significant risks associated with taking Fosamax. The running of any applicable Statute of Limitations has been tolled by reason of Defendants' fraudulent concealment.
- As a result of Defendants' actions, Plaintiff Jennifer Bogard and her 44. prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff Jennifer Bogard had been exposed to the risk identified in this complaint, and that those risks were the direct and proximate result of Defendants' acts, omissions, and misrepresentations.

FIRST CAUSE OF ACTION (Negligence)

- Plaintiffs restate the allegations set forth above as if fully rewritten 45. herein.
- 46. Defendants owed Plaintiff Jennifer Bogard, and other consumers, a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and selling Fosamax.
- Defendants failed to exercise due care under the circumstances and 47. therefore breached this duty by:
- Failing to properly and thoroughly test Fosamax before a. releasing the drug to market;
- Failing to properly and thoroughly analyze the data resulting b. from the pre-marketing tests of Fosamax;
- Failing to conduct sufficient post-marked testing and c. surveillance of Fosamax;

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d. Designing, manufacturing, marketing. advertising. distributing, and selling Fosamax to consumers, including Plaintiff Jennifer Bogard, without an adequate warning of the significant and dangerous risks of Fosamax and without proper instructions to avoid the harm which could foreseeably occur as a result of using the drug:

- Failing to exercise due care when advertising and promoting e. Fosamax: and,
- Negligently continuing to manufacture, market, advertise, and f. distribute Fosamax after Defendants knew or should have known of its adverse effects.
- As a direct and proximate consequence of Defendants' actions, 48. omissions, and misrepresentations, Plaintiff Jennifer Bogard suffered serious personal In addition, Plaintiff Jennifer Bogard required and will continue to require healthcare and services. Plaintiff Jennifer Bogard has incurred and will continue to incur medical and related expenses. Plaintiff Jennifer Bogard also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff Jennifer Bogard has incurred and will continue to incur mental and physical pain and suffering. Plaintiff has suffered loss of wages and wage-earning capacity.
- Defendants' conduct as described above was committed with 49. knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff Jennifer Bogard, thereby entitling Plaintiff to punitive damages so as to punish Defendants and deter them from similar conduct in the future.

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WHEREFORE, Plaintiffs demand judgment against Defendants and seek compensatory damages, and exemplary and punitive damages together with interest, the costs of suit, attorneys' fees and such other and future relief as the Court deems just and proper.

SECOND CAUSE OF ACTION (Strict Liability)

- 50. Plaintiffs restate the allegations set forth above as if fully rewritten herein.
- 51. Defendants manufactured, sold, distributed, marketed, and/or supplied Fosamax in a defective and unreasonably dangerous condition to consumer, including Plaintiff Jennifer Bogard.
- 52. Defendants designed, manufactured, sold, distributed, supplied marketed, and/or promoted Fosamax, which was expected to reach and did in fact reach consumers, including Plaintiff Jennifer Bogard, without substantial change in the condition in which it was manufactured and sold by Defendants.
- 53. Plaintiff Jennifer Bogard used Fosamax as prescribed and in a manner normally intended, recommended, promoted and marketed by Defendants.
- 54. Fosamax failed to perform safely when used by ordinary consumers. including Plaintiff Jennifer Bogard, including when it was used as intended and in a reasonably foreseeable manner.
- 55. Fosamax was defective in its design and was unreasonably dangerous in that its unforeseeable risks exceeded the benefits associated with its design or formulation.
- 56. Fosamax was defective in design or formulation in that it posed a greater likelihood of injury than other similar medications and was more dangerous than an

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ordinary consumer could reasonably foresee or anticipate.

- Fosamax was defective in its design and was unreasonably dangerous 57. in that it neither bore nor was packaged with nor accompanied by warnings adequate to alert consumers, including Plaintiff Jennifer Bogard, of the risks described herein, including, but not limited to, the risk of osteonecrosis of the jaw.
- Although Defendants knew or should have known of the defective 58. nature of Fosamax, it continued to design, manufacture, market, and sell Fosamax so as to maximize sales and profits at the expense of the public health and safety. By so acting, Defendants acted with conscious and deliberate disregard of the foreseeable harm caused by Fosamax.
- 59. Plaintiff Jennifer Bogard could not, through the exercise of reasonable care, have discovered Fosamax's defects or perceived the dangers posed by the drug.
- As a direct and proximate consequence of Defendants' conduct, 60 Plaintiff Jennifer Bogard suffered serious personal injuries. In addition, Plaintiff Jennifer Bogard required and will continue to require healthcare. Plaintiff Jennifer Bogard has incurred and will continue to incur medical and related expenses, Plaintiff Jennifer Bogard also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages Plaintiff Jennifer Bogard direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff Jennifer Bogard has incurred and will continue to incur mental and physical pain and suffering. Plaintiff Jennifer Bogard has suffered loss of wages and wage-earning capacity.
 - 61. Defendants' conduct as described above was committed with

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knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff Jennifer Bogard, thereby entitling Plaintiff to punitive damages so as to punish Defendants and deter them from similar conduct in the future.

WHEREFORE, Plaintiffs demand judgment against Defendants and seek compensatory damages, and exemplary and punitive damages together with interest, the costs of suit, attorneys' fees and such other and future relief as the Court deems just and proper.

THIRD CAUSE OF ACTION (Breach of Express Warranty)

- Plaintiffs restate the allegations set forth above as if fully rewritten 62. herein.
- Defendants expressly represented to Plaintiff Jennifer Bogard and 63. other consumers and the medical community that Fosamax was safe and fit for its intended purposes, that it was of merchantable quality, that it did not produce any dangerous side effects, and that it was adequately tested.
- 64. Fosamax does not conform to Defendants' express representations because it is not safe, has numerous and serious side effects, and causes severe and permanent injuries.
- 65. At all relevant times Fosamax did not perform as safely as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.
- 66. Plaintiff Jennifer Bogard, other consumers, and the medical community relied upon Defendants' express warranties.
 - As a direct and proximate result of Defendants' actions, Plaintiff 67.

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Jennifer Bogard suffered serious personal injuries. In addition, Plaintiff Jennifer Bogard required and will continue to require healthcare and services. Plaintiff Jennifer Bogard has incurred and will continue to incur medical and related expenses. Plaintiff Jennifer Bogard also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff Jennifer Bogard's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff Jennifer Bogard has incurred and will continue to incur mental and physical pain and suffering. Plaintiff has suffered loss of wages and wage-earning capacity.

68. Defendants' conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff Jennifer Bogard, thereby entitling Plaintiff to punitive damages so as to punish Defendants and deter them from similar conduct in the future.

WHEREFORE, Plaintiffs demand judgment against Defendants and seek compensatory damages, and exemplary and punitive damages together with interest, the costs of suit, attorneys' fees and such other and future relief as the Court deems just and proper.

FOURTH CAUSE OF ACTION (Breach of Implied Warranty)

- 69. Plaintiffs restate the allegations set forth above as if fully rewritten herein.
- 70. Defendants manufactured, distributed, advertised, promoted and sold Fosamax.

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- At all relevant times. Defendants knew of the use for which Fosamax 71. was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.
- Defendants were aware that consumers, including Plaintiff Jennifer 72. Bogard, would use Fosamax for treatment of osteoporosis and for other purposes.
- 73. Plaintiff Jennifer Bogard and the medical community reasonably relied upon the judgment and sensibility of Defendants to sell Fosamax only if it was indeed of merchantable quality and safe and fit for its intended use.
- Defendants breached their implied warranty to consumers, including 74. Plaintiff Jennifer Bogard; Fosamax was not of merchantable quality or safe and fit for its intended use.
- Consumers, including Plaintiff Jennifer Bogard, and the medical 75. community, reasonably relied upon Defendants' implied warranty for Fosamax.
- Fosamax reached consumers without substantial change in the 76. condition in which it was manufactured and sold by Defendants.
- As a direct and proximate result of Defendants' actions, Plaintiff 77. Jennifer Bogard suffered serious personal injuries. In addition, Plaintiff Jennifer Bogard required and will continue to require healthcare services. Plaintiff Jennifer Bogard has incurred and will continue to incur medical and related expenses. Plaintiff Jennifer Bogard has suffered and will continue to suffer diminished capacity for enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff Jennifer Bogard's direct medical losses and cost include care for hospitalization, physician care, monitoring, treatment, medications and supplies. Plaintiff Jennifer Bogard has incurred and will continue to incur mental and physical pain and suffering. Plaintiff has

suffered loss of wages and wage-earning capacity.

78. Defendants' conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and rights and safety of consumers such as Plaintiff Jennifer Bogard, thereby entitling Plaintiff Jennifer Bogard to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

WHEREFORE, Plaintiffs demand judgment against Defendants and seek compensatory damages, and exemplary and punitive damages together with interest, the costs of suit, attorneys' fees and such other and future relief as the Court deems just and proper.

FIFTH CAUSE OF ACTION (Fraudulent Misrepresentation)

- 79. Plaintiffs restate the allegations set forth above as if fully rewritten herein.
- 80. Defendants made fraudulent misrepresentations with respect to Fosamax in the following particulars:
- a. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that Fosamax had been tested and found to be safe and effective for the treatment and prevention of osteoporosis; and
- b. Defendants represented that Fosamax was safer than other alternative medications.
- 81. Defendants knew that their representations were false, yet they willfully, wantonly, and recklessly disregarded its obligation to provide truthful representations regarding the safety and risk of Fosamax to consumers, including Plaintiff

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Jennifer Bogard, and the medical community.

- 82. The representations were made by Defendants with the intent that doctors and patients, including Plaintiff Jennifer Bogard, rely upon them.
- 83. Defendants' representations were made with the intent of defrauding and deceiving Plaintiff Jennifer Bogard, other consumers, and the medical community to induce and encourage the sale of Fosamax.
 - 84. Plaintiff's doctors, and others relied upon the representations.
- 85. Defendants' fraudulent representations evinced its callous, reckless. willful, and depraved indifference to the health, safety and welfare of consumers, including Plaintiff Jennifer Bogard.
- As a direct and proximate result, Plaintiff Jennifer Bogard suffered 86. serious personal injuries. In addition, Plaintiff Jennifer Bogard required and will continue to require healthcare services. Plaintiff Jennifer Bogard has incurred and will continue to incur medical and related expenses. Plaintiff Jennifer Bogard has suffered and will continue to suffer diminished capacity for enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and cost include care for hospitalization, physician care, monitoring, treatment, medications and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering. Plaintiff has suffered loss of wages and wage-earning capacity.
- 87. Defendants' conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff Jennifer Bogard, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

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A Professional Corporation

WHEREFORE, Plaintiffs demand judgment against Defendants and seek compensatory damages, and exemplary and punitive damages together with interest, the costs of suit, attorneys' fees and such other and future relief as the Court deems just and proper.

SIXTH CAUSE OF THE ACTION (Fraudulent Concealment)

- 88. Plaintiffs restate the allegations set forth above as if fully rewritten herein.
- Defendants made fraudulent misrepresentations with respect to 89. Fosamax in the following particulars:
- Defendants represented through its labeling, advertising, a. marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that Fosamax was safe and fraudulently withheld and concealed information about the substantial risks of using Fosamax; and
- b. Defendants represented that Fosamax was safer than other alternative medications and fraudulently concealed information which demonstrated that Fosamax was not safer than alternatives available on the market.
- 90. Defendants had sole access to material facts concerning the dangers and unreasonable risks of Fosamax.
- 91. The concealment of information by Defendants about the risks of Fosamax was intentional, and the representations made by Defendants were known by Defendants to be false.
- 92. The concealment of information and the misrepresentations about Fosamax were made by Defendants with the intent that doctors and patients including Plaintiff Jennifer Bogard, rely upon them.

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Plaintiff's doctors, and others relied upon the representations and 93 were unaware of the substantial dental and oral risks of Fosamax which Defendants concealed from Plaintiff's doctors and Plaintiff.

As a direct and proximate result of Defendants' fraudulent 94. concealment and misrepresentation, Plaintiff suffered serious personal injuries. In addition, Plaintiff required and will continue to require healthcare services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff has suffered and will continue to suffer diminished capacity for enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and cost include care for hospitalization, physician care, monitoring, treatment, medications and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering. Plaintiff has suffered loss of wages and wage-earning capacity.

95. Defendants' conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

WHEREFORE, Plaintiffs demand judgment against Defendants and seek compensatory damages, and exemplary and punitive damages together with interest, the costs of suit, attorneys' fees and such other and future relief as the Court deems just and proper.

SEVENTH CAUSE OF ACTION (Violation of Business & Profession Code Section 17200)

96. Plaintiffs restate the allegations set forth above as it fully rewritten herein.

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97. Plaintiffs are informed and believe and allege that Defendants, by the acts and misconduct alleged herein, violated Business and Professions Code sections 17200.

- 98. California Business & Professions Code Section 17200 provides that unfair competition shall mean and include "all unlawful, unfair or fraudulent business practices and unfair, deceptive, untrue or misleading advertising."
- 99. The acts and practices described herein were and are likely to mislead the general public and therefore constitute unfair business practices within the meaning of Business & Professions Code Section 17200. The acts and untrue and misleading advertising set forth in presiding paragraphs are incorporated by reference and are, by definition, violations of Business & Professions Code Section 17200. This conduct includes, but is not limited to:
- Representing to Plaintiff, Plaintiff's physicians and the a. general public that Fosamax was safe, fit and effective for human consumption, knowing that said representations were false, and concealing from the Plaintiff, Plaintiff's physicians and the general public that Fosamax has a serious propensity to cause injuries to users;
- b. Engaging in advertising programs designed to create the image, impression and belief by consumers, physicians and others that the use of Fosamax was safe for human use, had fewer side effects and adverse reactions than other methods for treating osteoporosis, osteopenia, and Paget's Disease, constituted a convenient, safe form for treating osteoporosis, osteopenia, and Paget's Disease and would not interfere with daily life, even though the Defendants knew these to be false, and even though the Defendants had no reasonable grounds to believe them to be true:
- Purposely downplaying and understating the health hazards c. and risks associated with Fosamax; and

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	d.	Issuing promotional literature deceiving potential users of
Fosamax by relaying	positive	e information and manipulating statistics to suggest widespread
acceptability, while o	lownpla	ying the known adverse and serious health effects and
concealing material r	elevant	information regarding the safety of Fosamax.

- These practices constitute unlawful, unfair and fraudulent business 100. acts or practices, within the meaning of California Business & Professions Code Section 17200, as well as unfair, deceptive, untrue and misleading advertising as prohibited by California Business & Professions Code Section 17500, as set forth herein.
- 101. The unlawful, unfair and fraudulent business practices of Defendants described above present a continuing threat to members of the public in that Defendants continue to engage in the conduct described therein.
- As a result of their conduct described above, Defendants have been 102. unjustly enriched. Specifically, Defendants have been unjustly enriched by receipt of hundreds of millions of dollars in ill-gotten gains from the sale and prescription of Fosamax in California, and other states, sold in large part as a result of the acts and omissions described herein.
- 103. Because of the fraudulent misrepresentations made by Defendants as detailed above, and the inherently unfair practice of committing a fraud against Plaintiff and public by intentionally misrepresenting and concealing material information, the acts of Defendant described herein constitute unfair or fraudulent business practices.
- 104. Plaintiffs, pursuant to California Business & Professions Code Section 17203, seek an order of this court compelling the Defendants to provide restitution, and to disgorge the monies collected and profits realized by Defendants, and each of them, as a result of their unfair business practices.
 - 105. Defendants' acts were willful, wanton, reckless and fraudulent;

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hence, Plaintiff is entitled to exemplary damages, inter alia.

WHEREFORE, Plaintiffs demand judgment against Defendants and seek compensatory damages, disgorgement, restitution, and exemplary and punitive damages together with interest, the costs of suit, attorneys' fees and such other and future relief as the Court deems just and proper.

EIGHTH CAUSE OF ACTION (Violation of Business & Profession Code Section 17500)

- 106. Plaintiffs restate the allegations set forth above as it fully rewritten herein.
- Plaintiffs are informed and believe and thereon allege that 107. Defendants, by the acts and misconduct alleged herein, violated Business & Professions Code Section 17500.
- 108. Plaintiffs hereby seek restitution, as well as and punitive damages against Defendants for their violations of section 17500.
- California Business & Professions Code section 17500 provides that 109. it is unlawful for any person, firm, corporation or association to dispose of property or perform services, or to induce the public to enter into any obligation relating thereto, through the use of untrue or misleading statements.
- At all times herein mentioned, Defendants have committed the acts of disseminating untrue and misleading statements as defined by Business & Professions Code Section 17500 by engaging in the following acts and practices with intent to induce members of the public to purchase and use Fosamax:
- Representing to Plaintiff, Plaintiff's physicians and the general public that Fosamax was safe, fit and effective for human consumption, knowing that said representations were false, and concealing from the Plaintiff, Plaintiff's physicians

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and the general public that Fosamax have a serious propensity to cause injuries to users;

- Engaging in advertising programs designed to create the b. image, impression and belief by consumers, physicians and others that the use of Fosamax was safe for human use, had fewer side effects and adverse reactions than other methods for treating mental illness, constituted a convenient, safe form for treating mental illness and would not interfere with daily life, even though the Defendants knew these to be false, and even though the Defendants had no reasonable grounds to believe them to be true;
- c. Purposely downplaying and understating the health hazards and risks associated with Fosamax; and
- Issuing promotional literature deceiving potential users of Fosamax by relaying positive information and manipulating statistics to suggest widespread acceptability, while downplaying the known adverse and serious health effects and concealing material relevant information regarding the safety of Fosamax.
- 111. The foregoing practices constitute false and misleading advertising within the meaning of California Business & Professions Code Section 17500.
- As a result of its false and misleading statements described above. Defendants have been and will be unjustly enriched. Specifically, Defendants have been unjustly enriched by receipt of hundreds of millions of dollars from the sale and prescription of Fosamax in California and other states, sold in large part as a result of the false or misleading statements described herein.
- 113. Pursuant to California Business & Professions Code Section 17535. Plaintiffs seek an order of this court compelling the Defendants to provide restitution, and to disgorge the monies collected and profits realized by Defendants, and each of them, as a result of their unfair business practices, and injunctive relief calling for Defendants to cease such unfair business practices in the future.

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WHEREFORE, Plaintiffs demand judgment against Defendants and seek compensatory damages, disgorgement, restitution, and exemplary and punitive damages together with interest, the costs of suit, attorneys' fees and such other and future relief as the Court deems just and proper.

NINTH CAUSE OF ACTION (Loss of Consortium)

- 114. Plaintiffs restate the allegations set forth above as if fully rewritten herein.
 - 115. Plaintiff Robert Bogard bring this cause of action.
- 116. By reason of the injuries sustained by Plaintiff Jennifer Bogard, Plaintiff Robert Bogard has been and will continue to be deprived of consortium, society, comfort, protection, and service, thereby causing and continuing to cause said Plaintiff grief, sorrow, mental anguish, emotional distress and pain and suffering.

WHEREFORE, Plaintiffs demand judgment against Defendants and seek compensatory damages, and exemplary and punitive damages together with interest, the costs of suit, attorneys' fees and such other and future relief as the Court deems just and proper.

TENTH CAUSE OF ACTION (Punitive Damages)

- 117. Plaintiffs restate the allegations set forth above as if fully rewritten herein.
- 118. Defendants have repeatedly engaged in a pattern of conduct of deliberately avoiding FDA recommendations as to public hazards which should be warned about.
- 119. For instance, in March, 2000, Merck completed a study called VIGOR (Vioxx Gastrointestinal Outcomes Research) relating to its prescription Cox-2

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inhibitor, Vioxx. The VIGOR study showed that Vioxx patients had more than double the rate of serious cardiovascular problems than those on Naproxen, an older non-steroidal antiinflammatory drug. The study was published in the New England Journal of Medicine.

- In September, 2001, the FDA warned Merck to stop misleading 120. doctors about Vioxx's effect on the cardiovascular system. Merck was admonished to stop minimizing the risks of the drug in its marketing. Despite that, Merck refused to adequately warn physicians and patients about the risk of heart attacks and Vioxx.
- On August 25, 2004, a representative from the FDA presented results 121. of a database analysis of 1.4 million patients. The analysis demonstrated that Vioxx users were more likely to suffer a heart attack or sudden cardiac death than those taking Celebrex or older non-steroidal drugs. The FDA representative concluded that Vioxx was linked to more than 27,000 heart attacks or sudden cardiac deaths nationwide from the time in came on the market in 1999 through 2003.
- On August 26, 2004, Merck released a press statement which refuted 122. the FDA analysis and restated Merck's support for the cardiovascular safety of Vioxx.
- 123. On September 30, 2004, Merck recalled Vioxx from the market, after having to halt the APPROV (Adenomatous Polyp Prevention On Vioxx) study. The study was underway to evaluate the use of Vioxx for recurrent colon polyps. The researchers found an alarming number of cardiovascular events among the drug's users in the APPROV study.
- At that same time, Defendants were aware that the FDA, as of 124. August 24, 2004, was advising Merck to warn about the risk of osteonecrosis of the jaw for its Fosamax patients. Because Merck knew that its blockbuster drug Vioxx was about to be pulled from the market, placing more importance on the more than \$3 billion annual sales of Fosamax, Merck deliberately chose not to amend its packaging of Fosamax to include

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the risk of osteonecrosis of the jaw, fearing that such a warning would result in reduced revenues for its second largest income producer, Fosamax.

Merck's acts were willful and malicious in that Merck's conduct was 125. carried on with a conscious disregard for the safety and rights of Plaintiff and all others taking Fosamax. Merck's unconscionable conduct thereby warrants an assessment of exemplary and punitive damages against Merck in an amount appropriate to punish Merck and deter similar conduct in the future.

WHEREFORE, Plaintiffs demand judgment against Defendants and seek compensatory damages, and exemplary and punitive damages together with interest, the costs of suit, attorneys' fees and such other and future relief as the Court deems just and proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against Defendants. jointly and/or severally, as follows:

- For general damages in an amount to be proven at the time of trial;
- b. For special damages in an amount to be proven at time of trial:
- c. For exemplary and punitive damages in an amount to be proven at the time of trial, and sufficient to punish Defendants or to deter Defendants and others from repeating the injurious conduct alleged herein;
- d. For prejudgment and post-judgment interest on the above general and special damages;
 - For disgorgement; e.
 - f. For restitution:
 - For costs and attorneys' fees; and g.
 - h. All other relief that Plaintiffs may be entitled to at equity or at law.

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DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury on all claims so triable in this action.

Dated: November 1, 2006

Respectfully submitted,

Ву

Nancy Hersh, Esq.
Mark E. Burton, Esq.
Rachel Abrams, Esq.
HERSH & HERSH
A Professional Corporation
2080 Opera Plaza
601 Van Ness Avenue
San Francisco, CA 94102-6388
(415) 441-5544

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